UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,083	04/16/2004	Rashida A. Karmali	134.004	9955

7590 10/19/2006

Rashida A. Karmali
13th Floor
99 Wall Street
New York, NY 10005

EXAMINER	
HANDY, DWAYNE K	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/826,083	KARMALI, RASHIDA A.	
	Examiner	Art Unit	
	Dwayne K. Handy	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schramm et al. (5,935,864) in view of Nason (4,978,504) and further in view of Liotta et al. (5,942,407). This rejection was made in the previous Office Action (mailed 3/23/06). It remains in effect. Please see Response to Arguments below.

Response to Arguments

3. Applicant's arguments filed 7/21/06 have been fully considered but they are not persuasive. The previous rejection may be summarized as follows: Schramm teaches every element of the claims except for the materials, filter, colored reagents, and coated

capillary. Nason provides a teaching of plastic materials, a filter and colored reagents. Liotta provides a coated capillary

4. Applicant has argued that the addition of Liotta to the combined teachings of Schramm and Nason is not proper since Liotta is not relevant prior art (page 3, lines 14-23 of submitted Arguments). Applicant has also argued that hindsight would be required for one of ordinary skill in the art (Interview 10/16/06). The Examiner respectfully disagrees on both counts. The combined teachings of Schramm and Nason teach a collection device that collects a sample and reacts with a reagent to form a product. The product may then be analyzed by visual or optical means to determine the contents of the sample. Liotta also teaches the analysis of a sample by colorimetric or optical assay. . Applicant has also argued that Liotta does not, in fact, disclose the coated capillary. The Examiner disagrees. Liotta recites that a coated vacutainer or ***coated capillary pipette*** could be utilized in collecting the sample (column 12, lines 46-67).

Schramm and Nason teach colorimetric analysis of a sample collected through a capillary end portion (element 4 of Schramm). Liotta teaches the colorimetric analysis of a collected sample and in addition teaches that the sample may be collected through a sample collection device having a capillary element coated with a material that both stabilizes the sample and removes interfering metal cations through the use of chelating agents (column 12, lines 46-67). The Examiner submits that this is indeed relevant to the combined teachings of Schramm and Nason and that no hindsight is required.

Liotta clearly recites the use of a coated capillary in collecting the sample. Schramm and Nason teach a collection device that collects a sample through a capillary element (4) and then analyzes the sample by visual or optical means. The addition of the coated element from Liotta prevents metal ions in the sample from interfering with the optical analysis in Liotta. The Examiner submits this would be recognized by one of ordinary skill in the art as being an advantageous addition to the teachings of Schramm and Liotta. Adding the reagents to the inside of the entrance capillary would provide a stable sample that is free of interfering metal ions.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K. Handy whose telephone number is (571)-272-1259. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DKH
October 16, 2006

Jill Warden
Supervisory Patent Examiner
Technology Center 1700